

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in November 2013.

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### Original Approvals

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This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

#### NADA Number: 141-406

Trade Name: NexGard™  
Ingredients: Afoxolaner  
Sponsor: Merial Ltd.  
Approval Date: September 14, 2013  
Status: Rx  
Route: Oral  
Species: Dogs  
Drug Form: Chewable tablet  
Concentration: Each chewable contains 11.3 mg, 28.3 mg, 68 mg, or 136 mg afoxolaner.  
Indications: For the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of American dog tick (*Dermacentor variabilis*) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for 1 month.  
Exclusivity: 5 years

21 CFR 520.43

78 FR 66263-66265

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### Supplemental Approvals

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This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

#### NADA Number: 095-735

Trade Name: Rumensin®  
Ingredients: Monensin  
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.  
Approval Date: September 5, 2013

This supplement provides for the reduction in the minimum concentration of monensin in Type C medicated feeds for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers) from 25 to 15 grams per ton.

21 CFR 558.355

78 FR 66263-66265

#### NADA Number: 141-288

Trade Name: EXCENEL® RTU EZ  
Ingredients: Ceftiofur hydrochloride  
Sponsor: Zoetis Inc.  
Approval Date: September 13, 2013

This supplement provides for a reformulated product for use in swine and cattle, addition of a new route of administration (intramuscular injection) in cattle, change of withdrawal period in cattle, and a 250 mL vial size.

21 CFR 522.313b

78 FR 66263-66265

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### Sponsor Change

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The following corrections or additions to the list were published in the Federal Register in November 2013.

### ANADA Number: 200-555

Previous: Piedmont Animal Health  
New Sponsor: Bayer HealthCare LLC, Animal Health Division  
Drug Labeler Code: 000859  
*21 CFR 520.309*                      *78 FR 66263-66265*

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### Patent Additions

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### NADA Number: 141-258, 141-276, 141-278, 141-280, 141-282, 141-284

Patent number: 8,580,772  
Expiration Date: April 30, 2030

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### Patent Correction

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### NADA Number: 141-334

Original Patent number: 6,154,946  
Corrected Patent number: 6,514,946

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### Withdrawal of Approval

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### NADA Number: 007-891

Sponsor: Zoetis Inc.  
Trade Name: 3-Nitro®  
Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.530*                      *78 FR 69992-69994*

### NADA Number: 010-285

Sponsor: Zoetis Inc.  
Trade Name: Carb-O-Sep®  
Ingredients: Carbarsone

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.120*                      *78 FR 69992-69994*

### NADA Number: 092-953

Sponsor: Zoetis Inc.  
Trade Name: Roxarsone  
Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.530*                      *78 FR 69992-69994*

### NADA Number: 008-019

Sponsor: Fleming Laboratories, Inc.

## **Actions Taken by FDA Center for Veterinary Medicine**

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Trade Name: Pro-Gen  
Ingredients: Arsanilic acid

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.62*                      *78 FR 70496*